Senate Bill No. 962

CHAPTER 517

An act to amend Section 123371 of, and to add Section 124991 to, the Health and Safety Code, relating to umbilical cord blood.

[Approved by Governor October 11, 2007. Filed with Secretary of State October 11, 2007.]

LEGISLATIVE COUNSEL'S DIGEST

SB 962, Migden. Umbilical cord blood: research.

Existing law imposes various responsibilities upon the State Department of Public Health and prenatal care providers with respect to prenatal care, screening, and counseling.

Existing law, administered by the department, contains provisions governing the licensure of blood banks, including provisions relating to licensure or accreditation for purposes of umbilical cord blood banking. Existing law also requires the department to conduct the Umbilical Cord Blood Community Awareness Campaign, which, among other things, authorizes a primary prenatal care provider, as defined, to provide to a woman who is known to be pregnant, during the first prenatal visit, certain information developed by the department regarding her options with respect to umbilical cord blood banking.

Existing law establishes the Umbilical Cord Blood Education Account, in which private donations are collected and deposited for the purpose of funding the information developed by the department pursuant to the Umbilical Cord Blood Community Awareness Campaign, and requires these funds to be available upon a determination by the Director of Finance that sufficient private donations have been collected and deposited into the account.

Existing law, the Hereditary Disorders Act, requires the department to establish regulations and standards for a hereditary disorders program, including with respect to prenatal testing programs for newborns. A violation of these provisions is a crime.

Pursuant to this act, existing regulations require clinicians to provide all pregnant women, at the first prenatal visit, with information about the use and availability of prenatal screening for birth defects of the fetus. If a pregnant woman voluntarily requests prenatal screening, these regulations, among other things, require a clinician to make available to her the opportunity to read and sign a consent document, as specified.

Existing law also provides for the Birth Defects Monitoring Program, administered by the department, which includes the storage of pregnancy blood for research-related purposes. Existing law authorizes the department to charge a fee for prenatal screening, and requires the fees to be deposited

into the Birth Defects Monitoring Program Fund to be used, upon appropriation by the Legislature, to support the pregnancy blood sample storage, testing, and research activities of the Birth Defects Monitoring Program.

This bill would authorize a primary prenatal care provider to provide information required to be developed pursuant to the Umbilical Cord Blood Community Awareness Campaign to a woman who is known to be pregnant during the first prenatal visit.

The bill would also require, as part of the Hereditary Disorders Act, the department to provide any umbilical cord blood samples it receives pursuant to the Umbilical Cord Blood Community Awareness Campaign to the Birth Defects Monitoring Program, for storage and research, and would require the department to establish fees to be collected from researchers and health care providers, who have been approved by the department, to use the umbilical cord, pregnancy blood, and newborn blood samples for research, to cover the costs of administering the program. The bill would set forth the various duties of the department relating to collecting and storing the samples, and would require that information collected in connection with the samples be confidential, and be used solely for the purposes of the program, as specified. The bill would require these fees to be deposited into the Birth Defects Monitoring Program Fund, to be used by the department, upon appropriation by the Legislature, for purposes of paying the costs associated with the department's duties with respect to umbilical cord blood samples, as prescribed.

The Committee for the Protection of Human Subjects (CPHS) serves as the institutional review board for the California Health and Human Services Agency, for the purpose of assuring that research involving human subjects is conducted ethically and with minimum risk to participants.

This bill would require CPHS to determine if certain criteria relating to the security and confidentiality of a donor's personal information are met before umbilical cord blood samples that have been collected are released for research activities.

The bill would provide that these provisions shall only become operative if AB 34, of the 2007–08 Regular Session, is enacted and becomes operative on or before January 1, 2008.

By creating a new crime, this bill would create a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares that the removal and discarding of umbilical cord blood from a pregnant woman at the time of birth delivery, without the understanding and approval of the expectant families, is a growing concern to the people of this state.

SEC. 2. Section 123371 of the Health and Safety Code is amended to read:

123371. (a) (1) The State Department of Public Health shall develop standardized, objective information about umbilical cord blood donation that is sufficient to allow a pregnant woman to make an informed decision on whether to participate in a private or public umbilical cord blood banking program. The information developed by the department shall enable a pregnant woman to be informed of her option to do any of the following:

(A) Discard umbilical cord blood.

(B) Donate umbilical cord blood to a public umbilical cord blood bank.

(C) Store the umbilical cord blood in a family umbilical cord blood bank for the use by immediate and extended family members.

(D) Donate umbilical cord blood to research.

(2) The information developed pursuant to paragraph (1) shall include, but not be limited to, all of the following:

(A) The current and potential future medical uses of stored umbilical cord blood.

(B) The benefits and risks involved in umbilical cord blood banking.

(C) The medical process involved in umbilical cord blood banking.

(D) Medical or family history criteria that can impact a family's consideration of umbilical cord banking.

(E) An explanation of the differences between public and private umbilical cord blood banking.

(F) The availability and costs of public or private umbilical cord blood banks.

(G) Medical or family history criteria that can impact a family's consideration of umbilical cord blood banking.

(H) An explanation that the practices and policies of blood banks may vary with respect to accreditation, cord blood processing and storage methods, costs, and donor privacy.

(I) An explanation that pregnant women are not required to donate their umbilical cord blood for research purposes.

(b) The information provided by the department pursuant to subdivision (a) shall be made available in Cantonese, English, Spanish, and Vietnamese, and shall be updated by the department as needed.

(c) The information provided by the department pursuant to subdivision (a) shall be made available on the Internet Web sites of the licensing boards that have oversight over primary prenatal care providers.

(d) (1) A primary prenatal care provider of a woman who is known to be pregnant may, during the first prenatal visit, provide the information required by subdivision (a) to the pregnant woman.

(2) For purposes of this article, a "prenatal care provider" means a health care provider licensed pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, or pursuant to an initiative act referred to in that division, who provides prenatal medical care within his or her scope of practice.

(e) The department shall only implement this article upon a determination by the Director of Finance, that sufficient private donations have been collected and deposited into the Umbilical Cord Blood Education Account, which is hereby created in the State Treasury. The moneys in the account shall be available, upon appropriation by the Legislature, for the purposes of this article. No public funds shall be used to implement this article. If sufficient funds are collected and deposited into the account, the Director of Finance shall file a written notice thereof with the Secretary of State.

SEC. 3. Section 124991 is added to the Health and Safety Code, to read:

124991. (a) (1) The State Department of Public Health shall provide any umbilical cord blood samples it receives pursuant to Section 123371 to the Birth Defects Monitoring Program for storage and research. In administering this section the department shall ensure that the Birth Defects Monitoring Program meets at least one of the following conditions:

(A) The fees paid by researchers, investigators, and health care services providers pursuant to subdivision (c) shall be used to cover the cost of collecting and storing blood, including umbilical cord blood.

(B) The department receives confirmation that an investigator, researcher, or health care provider has requested umbilical cord blood samples for research or has requested cord blood samples to be included within a request for pregnancy and newborn blood samples through the program.

(C) The department receives federal grant moneys to pay for initial startup costs for the collection and storage of umbilical cord blood samples.

(2) The department may limit the number of units the program collects each year.

(b) (1) All information relating to umbilical cord blood samples collected and utilized by the Birth Defects Monitoring Program shall be confidential, and shall be used solely for the purposes of the program. Access to confidential information shall be limited to authorized persons who agree, in writing, to maintain the confidentiality of that information.

(2) The department shall maintain an accurate record of all persons who are given confidential information pursuant to this section, and any disclosure of confidential information shall be made only upon written agreement that the information will be kept confidential, used for its approved purpose, and not be further disclosed.

(3) Any person who, in violation of a written agreement to maintain confidentiality, discloses any information provided pursuant to this section, or who uses information provided pursuant to this section in a manner other than as approved pursuant to this section may be denied further access to any confidential information maintained by the department, and shall be subject to a civil penalty not exceeding one thousand dollars ($1,000). The penalty provided in this section shall not be construed as to limit or otherwise

restrict any remedy, provisional or otherwise, provided by law for the benefit of the department or any other person covered by this section.

(c) In order to implement this program, the department shall establish fees of an amount that shall not exceed the costs of administering the program, which the department shall collect from researchers and health care providers who have been approved by the department and who seek to use the following types of blood samples, collected by the Birth Defects Monitoring Program, for research:

(1) Umbilical cord blood.

(2) Pregnancy blood.

(3) Newborn blood.

(d) Fees collected pursuant to subdivision (c) shall be deposited into the Birth Defects Monitoring Program Fund created pursuant to paragraph (7) of subdivision (b) of Section 124977. Moneys deposited into the fund pursuant to this section may be used by the department, upon appropriation by the Legislature, for the purposes specified in subdivision (e).

(e) Moneys in the fund shall be used for the costs related to data management, including data linkage and entry, and umbilical cord blood storage, retrieval, processing, inventory, and shipping.

(f) The department shall adopt rules and regulations pursuant to existing requirements in the Birth Defects Monitoring Program, as set forth in Chapter 1 (commencing with Section 103825) of Part 2 of Division 102.

(g) The department, health care providers, and local health departments shall maintain the confidentiality of patient information in accordance with existing law and in the same manner as other medical record information with patient identification that they possess, and shall use the information only for the following purposes:

(1) Research to identify risk factors for children's and women's diseases.

(2) Research to develop and evaluate screening tests.

(3) Research to develop and evaluate prevention strategies.

(4) Research to develop and evaluate treatments.

(h) (1) For purposes of ensuring the security of a donor's personal information, before any umbilical cord blood samples are released pursuant to this section for research purposes, the State Committee for the Protection of Human Subjects (CPHS) shall determine if all of the following criteria have been met:

(A) The Birth Defects Monitoring Program contractors or other entities approved by the department have provided a plan sufficient to protect personal information from improper use and disclosures, including sufficient administrative, physical, and technical safeguards to protect personal information from reasonable anticipated threats to the security or confidentiality of the information.

(B) The Birth Defects Monitoring Program contractors or other entities approved by the department have provided a sufficient plan to destroy or return all personal information as soon as it is no longer needed for the research activity, unless the program contractors or other entities approved by the department have demonstrated an ongoing need for the personal

information for the research activity and have provided a long-term plan sufficient to protect the confidentiality of that information.

(C) The Birth Defects Monitoring Program contractors or other entities approved by the department have provided sufficient written assurances that the personal information will not be reused or disclosed to any other person or entity, or used in any manner not approved in the research protocol, except as required by law or for authorized oversight of the research activity.

(2) As part of its review and approval of the research activity for the purpose of protecting personal information held in agency databases, CPHS shall accomplish at least all of the following:

(A) Determine whether the requested personal information is needed to conduct the research.

(B) Permit access to personal information only if it is needed for the research activity.

(C) Permit access only to the minimum necessary personal information needed for the research activity.

(D) Require the assignment of unique subject codes that are not derived from personal information in lieu of social security numbers if the research can still be conducted without social security numbers.

(E) If feasible, and if cost, time, and technical expertise permit, require the agency to conduct a portion of the data processing for the researcher to minimize the release of personal information.

(i) In addition to the fees described in subdivision (c), the department may bill a researcher for the costs associated with the department's process of protecting personal information, including, but not limited to, the department's costs for conducting a portion of the data processing for the researcher, removing personal information, encrypting or otherwise securing personal information, or assigning subject codes.

(j) Nothing in this section shall prohibit the department from using its existing authority to enter into written agreements to enable other institutional review boards to approve research activities, projects or classes of projects for the department, provided the data security requirements set forth in this section are satisfied.

SEC. 3. This act shall only become operative if Assembly Bill 34, of the 2007–08 Regular Session, is enacted and becomes operative on or before January 1, 2008.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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